

REMARKS

Applicant has received and carefully reviewed the Office Action mailed April 27, 2010. Applicant respectfully traverses (and does not concede) all objections, rejections, and adverse assertions made by the Examiner. With this paper, claim 13 has been amended. Support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added. Claims 13 and 15-28 remain pending. Favorable consideration of the above amendments and the following remarks is respectfully requested.

Allowed Claims

Claims 18-20 have been indicated as allowed. Applicant thanks the Examiner for the favorable consideration of these claims.

Claim Rejections under 35 U.S.C. § 103(a)

Claims 13, 15-17 and 21-28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Pfenninger (U.S. Patent No. 5,306,247) in view of Allman et al. (U.S. Patent No. 6,346,093). Applicant respectfully traverses the rejection.

Independent claim 13, as amended, recites:

13. A single lumen microcatheter, comprising:

an elongate shaft having a distal end and a proximal end, the elongate shaft having an outer surface and an inner surface, the inner surface defining a single lumen extending from the proximal end to the distal end of the elongate shaft and fluidly connecting the proximal end to an opening at the distal end of the elongate shaft;

an elongate guidewire port positioned proximal of the distal end of the elongate shaft, the elongate guidewire port extending from the inner surface of the elongate shaft to the outer surface of the elongate shaft; and

a polymer sheath disposed over the elongate guidewire port, the polymer sheath having an inner surface and an outer surface, the polymer sheath having a length measured from a proximal end of the polymer sheath to a distal end of the polymer sheath, the polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath, the slit disposed parallel to a longitudinal axis of the elongate shaft, the slit having a length measured parallel to the length of the polymer sheath and parallel to the longitudinal axis of the elongate shaft, the length of the slit being less than the length of the polymer sheath such that the slit extends along only a portion of the length of the polymer sheath, the passage in communication with the elongate guidewire port, wherein the passage is configured to permit guidewire access through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage; and

wherein when no guidewire is provided through the passage, the single lumen is substantially fluid tight from the proximal end of the elongate shaft to the opening at the distal end of the elongate shaft.

Neither Pfenninger nor Allman et al., taken alone or in combination, appear to teach or suggest such a microcatheter. In formulating the rejection, the Examiner asserts, "Pfenninger discloses the claimed invention except the longitudinal slit configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided." Applicant respectfully disagrees. Pfenninger appears to disclose a balloon catheter including an inflation lumen and a guidewire lumen. The guidewire lumen and inflation lumen appear to be disposed coaxially within the proximal portion of the catheter shaft and side-by-side in the distal portion of the catheter shaft. Pfenninger further appears to disclose the catheter shaft may include an opening disposed in the side of the catheter shaft for receiving the guidewire into the guidewire lumen at a location distal of the proximal end. The catheter shaft appears to include an outlet opening (9) for receiving the guidewire. Pfenninger appears to disclose the outlet is formed at the distal end of the proximal portion of the catheter shaft. The outlet appears to be disposed through the wall of the guidewire lumen as well as the wall of the proximal portion of the inflation lumen.

In formulating the rejection, the Examiner appears to assert the outlet of Pfenninger is equivalent to both the presently claimed elongate guidewire port and the passage in the sheath. Applicant respectfully disagrees. As can be seen, the passage in the sheath as currently claimed comprises an angled slit. As one of ordinary skill in the art may be well aware, a slit is commonly used to define a narrow cut or opening. For example, Merriam-Webster defines slit as "a long narrow cut or opening" (<http://www.merriam-webster.com/dictionary/slit>, accessed July 2, 2010). The intended meaning of the word slit is further evidenced by the description as well as the figures. See, for example, Figure 7 of the present application. Furthermore, the Examiner appears to assert that because the side wall of the outlet of Pfenninger is angled, Pfenninger disclose an angled slit. Clearly, an angled wall cannot be equated to the presently claimed slit.

Moreover, nothing in Pfenninger appears to teach or suggest "the passage is configured to permit guidewire access through the elongate guidewire port while remaining substantially fluid tight in use when no guidewire is provided through the passage" or "when no guidewire is provided through the passage, the single lumen is substantially fluid tight from the proximal end

of the elongate shaft to the opening at the distal end of the elongate shaft” as currently claimed. Nowhere does Pfenninger appear to teach or suggest any structure that may be capable of providing a substantially fluid tight guidewire port as currently claimed. Furthermore, Pfenninger appears to teach away from a fluid-tight guidewire lumen as evidenced by the side holes disposed distally of the outlet.

The Examiner appears to be relying on Allman et al. as disclosing the structure necessary to provide a substantially fluid tight seal. In formulating the rejection, the examiner asserts, “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Pfenninger with a longitudinal angled slit as taught by Allman, since such a modification would provide the system with a longitudinal slit for providing and allowing a guidewire to be radially slid into or out of the sheath assembly.” Pfenninger appears to disclose the outlet (oblong hole) is an advantageous structure. For example, Pfenninger disclose at column 7, lines 39-45, “The shape of the cutout thus produced does not lead to any stress peaks in the catheter shaft. This cutout shape may be so large and so long that guide wire 8 easily comes out of shaft 1 when threaded into the catheter without requiring devices such as a ramp, etc., in lumen 7 to facilitate the catheter coming out of the shaft.” Thus it is unclear why one would be motivated to change the shape or type of opening in the shaft of Pfenninger. The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) states, “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. Emphasis added; see page 14 of the April 30, 2007 Decision. The Court further stated, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” See page 14 of the April 30, 2007 Decision.

The Examiner further asserts:

Allman teaches that it is known to use a longitudinal angled slit configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided as set forth in paragraphs at column 8 lines 1-46 also see slit 118 in figure 4 and 4b or near 134 in figure 4c to provide and allow a guidewire to be radially slid into or out of the sheath assembly.

Applicant respectfully disagrees. After careful review, nothing in Allman et al. appears to teach or suggest an angled slit extending radially through the polymer sheath at an angle such that the

slit has a depth that is greater than a thickness of the polymer sheath as the Examiner appears to be asserting. Figure 4B of Allman et al. appears to show a slit extending at a 90° angle through the side wall such that the slit depth is equal to the wall thickness of the sheath. Nothing in the description of Allman et al. appears to indicate otherwise. Moreover, nothing in Allman et al. appears to teach or suggest the slit forms a substantially fluid tight seal. If the Examiner maintains the rejection, it is respectfully requested the Examiner explicitly point out where Allman et al. is considered as disclosing an angled slit.

Therefore, for at least these reasons, neither Pfenninger nor Allman et al., taken alone or in combination appear to teach or suggest the microcatheter as currently claimed. Thus, even if one were to combine Pfenninger and Allman et al., one would not arrive at the device as claimed. Furthermore, there appears to be no motivation, suggestion or other reason for one of ordinary skill in the art to modify Pfenninger or Allman et al. to arrive at the device as claimed. Reconsideration and withdrawal of the rejection are respectfully requested. For similar reasons, as well as others, independent claim 27 is also believed to be patentable over Pfenninger and Allman et al. Applicant submits that claims 15-17, 21-26, and 28 are also in condition for allowance as they depend from one of claims 13 or 27 and add significant limitations to further distinguish them from the prior art.

Conclusion

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Sean McFerran

By his Attorney,

Date: _____

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